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09/641,396	08/17/2000	Mikhail F. Gordeev	6270.N DV1	7157

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER

1639

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/641,396

Applicant(s)
Gordeev et al

Examiner
Mauri G. Baker, Ph.D.

Art Unit
1639



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Oct 28, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 44-48 is/are pending in the application

4a) Of the above, claim(s) 46 and 48 is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 44, 45, and 47 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other: _____

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit 1639.

1. The Response filed October 28, 2002 (Paper No. 9) is acknowledged. Claim 44 was amended, claims 1-6 and 49-54 were cancelled and no claims were added. Therefore, claims 44-48 are pending.

Election/Restriction

2. Applicant's election with traverse of Group II and election of species is acknowledged. The traversal is addressed below.
3. Applicant has cancelled the claims drawn to the other groups, thus the traversal is deemed moot. However, the requirement is still deemed proper and is therefore made FINAL.
4. Claims 46 and 48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic claim.
5. Therefore, claims 44, 45 and 47 are examined on the merits in this action.

Information Disclosure Statement

6. The Information Disclosure Statement (PTO-1449) filed August 17, 2000 is acknowledged; however, copies of the references cited therein cannot be located. It is recognized that these documents are supposed to be present in parent files 09/235,771 and 09/087,702; however, the references are missing from these files. The examiner is making efforts to locate these references; however, resubmission of these documents, if possible, by applicant would facilitate their consideration and would be greatly appreciated by the examiner. A signed copy of the PTO-1449 will be mailed as soon as the examiner obtains copies of the references.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 44, 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought,

he or she was in possession of the invention. Applicant's claims are directed to a "method of preparing combinatorial libraries of compounds of the formula 1b"; however, the library is made by "attaching a plurality of aryl oxazolidinones to a plurality of solid supports" in step a). The "aryl oxazolidinones" of step a) are not delineated by structure. There are a virtually unlimited number of compounds that would fall within the claimed genus of "aryl oxazolidinones". These compound could encompass widely varying functionalities and there is no clear definition of what functionalities the claimed "aryl oxazolidinone" starting compounds possess.

The instant specification discloses very limited examples of producing the claimed "aryl oxazolidinone" starting compounds and reactions thereof.

Adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that *applicant had possession of the full scope of the claimed invention*. The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

Method step a) is set forth in generic language only. However, the language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. A description of a compound in terms of its function fails to distinguish the compound from others having the same activity or function. A description of what a material does, rather than of

what it is, usually does not suffice. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

Therefore, for the above reasons, it is deemed that the disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Thus, there is not adequate support in the instant specification for the claimed invention.

9. Claims 44, 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for carrying out the claimed process under the following conditions: (1) using *particularly defined* aryl oxazolidinone starting compounds having an azido group thereon (as depicted in Figures 18 & 20, for example); (2) where the azide is converted to an iminophosphorane upon treating with Ph_3P and (3) the starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin; does not reasonably provide enablement for the “method of preparing combinatorial libraries of compounds of the formula 1b” using *any* “aryl oxazolidinones” attached to a resin by *any* method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant's specification how one might practice this invention under the following conditions: (1) using *particularly defined* aryl oxazolidinone starting compounds having an azido group thereon (as depicted in Figures 18 & 20, for example); (2) where the azide is converted to an iminophosphorane upon treating with Ph_3P and (3) the starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin; however, there is insufficient guidance as to how to carry out the claimed "method of preparing combinatorial libraries of compounds of the formula 1b" using *any* "aryl oxazolidinones" attached to a resin by *any* method. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: Applicant's claims are directed to a "method of preparing combinatorial libraries of compounds of the formula 1b"; however, the library is made by "attaching a plurality of aryl oxazolidinones to a plurality of solid supports" in step a) and further

functionalizing the starting materials in step b). The “aryl oxazolidinones” of step a) are not delineated by structure. Thus, the claims could read on a wide variety of structures of “aryl oxazolidinones”. Such represents very broad scope. In claim 44, no specifics on the attachment chemistry to the solid support is set forth whatsoever. It is noted that the dependent claims do define *portions* of the attachment chemistry to the solid support. However, it is the examiner’s position that no claims recite the enabled embodiments above with the necessary specificity and thus all claims under examination are included in this rejection.

The state of the prior art and the level of predictability in the art: The terminology “aryl oxazolidinones” in the prior art could represent a wide variety of compounds, with varying functionalities, and thus the level of predictability for how to make and use *any* such compounds in a solid phase synthesis scheme would be low. The structures of possible “aryl oxazolidinone” starting compounds are sufficiently diverse that one of ordinary skill would not be able to predict their structures. The instant specification also gives no guidance to permit one of skill in the art to devise strategies for attaching *any* such compounds to a solid support. Further research would be necessary to carry out the claimed invention with any “aryl oxazolidinone” since one of ordinary skill could not guess, *a priori*, how to make and use any such entities. The “predictability or lack thereof” in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the

claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed. The amount of direction provided by the inventor and the existence of working examples: The examples in the instant specification only show the claimed reaction under the following conditions: (1) using *particularly defined* aryl oxazolidinone starting compounds having an azido group thereon; (2) where the azide is converted to an iminophosphorane upon treating with Ph_3P and (3) the starting material is attached to a carbonyl containing resin by reaction of the iminophosphorane with the resin. See, for example, Figures 18 & 20 and page 31, line 14 through page 35, line 17 of the instant specification. The instant specification gives one skilled in the art no indication that one would have a reasonable expectation of success of using any other aryl oxazolidinone starting compounds or any other reaction conditions in the solid phase synthesis scheme due to the unpredictability of the necessary chemistry. Furthermore, as the claimed method involves a step b) of functionalizing the starting materials, this would be additionally unpredictable due to the omission of any structural details of the starting materials as claimed. In cases involving unpredictable factors, such as most chemical reactions and

physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. See *In re Fisher*, 57 CCPA 1099, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in carrying out the full scope of the claimed method due to the deficiencies described above. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make and/or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 44, 45 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is indefinite as it is incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: (1) the structure of the aryl oxazolidinone starting compounds; and (2) the nature of the functionalization reaction. Thus, one of ordinary skill would not know the metes and bounds of the claimed invention. See also rejections under 112, first paragraph above. Deficiency (1) brings about confusion as it is unclear how and where compounds are attached to the solid support (linkage site and linkage chemistry). Deficiency (2) is confusing because it is unclear how the compounds are functionalized due to the omission of any structural details of the starting materials. Note that claims 45 and 47 are included in this rejection as they are dependent from claim 44 and thus contain all of the limitations thereof.

Status of Claims/Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is

(703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
January 24, 2003

A handwritten signature in black ink, consisting of stylized, overlapping loops and a long horizontal stroke extending to the right.

MAURIE GARCIA BAKER, Ph.D.
PATENT EXAMINER